REMARKS

Claims 1-22 are pending. Claims 9-13 and 19-22 have been canceled; claims 1, 7, 8, 14, 17, and 18 have been amended.

The specification has been amended to acknowledge that Triton® is a registered trademark. Pursuant to the provisions of 37 C.F.R. §1.121(b)(1)(iii), a marked-up copy of amended specification is attached herewith as Appendix A.

Claims 9-13 and 19-22 have been canceled without prejudice. Applicant reserves the right to pursue these claims in a continuation or divisional application of this Application.

Claims 1, 7, 8, 14, 17, and 18 have been amended to clarify that the donor blood, blood product, or tissue found to be free of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal. Support for these amendments can be found throughout the specification, *e.g.*, at page 18, lines 2-13.

Claims 1, 7, 8, 14, 17, and 18 have also been amended to clarify that the binding agents bind to the Gram-positive and/or Gram-negative bacterial antigens in the sample. Support for these claim amendments can be found throughout the specification.

Pursuant to 37 C.F.R. §1.121(c)(1)(ii), a marked-up copy of amended claims 1, 7, 8, 14, 17, and 18 is attached herewith as Appendix B.

None of the above amendments adds any new matter to the Application as filed.

I. Specification

As requested by the Examiner, the specification has been amended to acknowledge that Triton® is a registered trademark.

II. Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1-22 stand rejected under 35 U.S.C. §112, second paragraph, because the term "clinically relevant amount of bacteria" is allegedly indefinite.

Applicant respectfully traverses this ground for rejection.

As the specification teaches at page 19, line 12 through page 20, line 3, a clinically relevant amount of bacteria is "[t]ypically, at the time of transfusion...greater

than 1 x 10^7 colony forming units (CFU) per ml of the blood or blood product." (see specification at page 19, line 21-22).

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground for rejection.

Claims 1, 7-9, 12-14, 17-19, and 21-22 stand rejected under 35 U.S.C. §112, second paragraph, as being unclear because the claims allegedly do not recite how to determine "binding of the set of binding agents to the sample."

Applicant has overcome this ground for rejection with the present amendments to claims 1, 7, 8, 14, 17, and 18. Accordingly, this ground for rejection should be reconsidered and withdrawn.

Claims 1-22 stand rejected under 35 U.S.C. §112, second paragraph, because the claims are allegedly incomplete for omitting essential steps.

Applicant respectfully traverses this ground for rejection.

The claims, as presently amended, require contacting a sample possibly containing a bacterial antigen with the binding agent(s) that specifically bind to the bacterial antigen, determining (*i.e.*, detecting) binding or no binding, and then identifying the "no binding" sample as being from a donor blood, blood product, or tissue useful for transfer to a recipient mammal.

Applicant respectfully avers that the claims are not incomplete for omitting essential steps. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground for rejection.

III. Rejections under 35 U.S.C. §102

Claims 1-2, 4, 6-8, and 14-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Young, U.S. Patent No. 5,698,198 (hereinafter "Young").

Applicant respectfully traverses this ground for rejection.

Applicant's invention stems from the discovery that donor blood, blood products, and tissue found to be free of a clinically relevant amount of bacteria can be transferred to a recipient mammal. Young provides novel antibodies that bind to Gram-negative

bacteria. However, nowhere does Young teach or even suggest using these antibodies to test blood, blood products, or tissue for the presence of a clinically relevant amount of bacteria, where the blood, blood product, or tissue found to be free of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal, as is required by the claims. Rather, Young teaches administering the Gram-negative specific antibodies to a human infected with a Gram-negative bacteria as method for treating that human.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground for rejection.

IV. Rejections under 35 U.S.C. §103

Claims 3 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Young in view of Richards, U.S. Patent No. 5,043,267 (hereinafter "Richards").

Applicant respectfully traverses this ground for rejection.

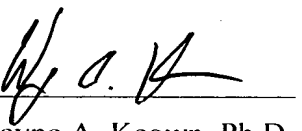
As discussed above, Young neither teaches nor suggests testing blood, blood products, or tissue for the presence of a clinically relevant amount of bacteria, where the blood, blood product, or tissue found to be free of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal, as is required by the claims. Nor does Richards cure this deficiency. Richards teaches methods to detect infection in a host animal; however, nowhere does Richards teach or suggest a method to screen donor blood, blood products, or tissue for the presence of a clinically relevant amount of bacteria, where the donor blood, blood product, or tissue found to be free of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal, as is required by the claims.

Since neither Young nor Richards teaches or suggests the same required limitation of the claims, their combination cannot render the claims obvious. Therefore, Applicant respectfully requests reconsideration and withdrawal of this ground for rejection.

For the reasons discussed above, Applicants respectfully submit that claims are now ready for allowance. If the Examiner believes that any discussion of this reply

would be helpful, the Examiner is invited to call the undersigned attorney by telephone at 781-938-1805.

Respectfully submitted,



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APPENDIX A

Marked-up Version of the Amended Specification Pursuant to 37 C.F.R. §1.121(c)(1)(ii)

At page 34, lines 21-28:

By "means for treating" is meant any method or treatment that exposes a binding site of the binding agent on the Gram-negative bacterial antigen or on the Gram-positive bacterial antigen thereof. Such means include, without limitation, physical manipulation, including homogenization (with, for example, a Dounce homogenizer), sonication, and boiling. Other "means for treating" include treatment of the sample with chemical solutions or compounds including, without limitation, detergents (*e.g.*, SDS or octoxynol, which is sold under the trademark [triton-X] Triton®), alkaline lysis solutions (*e.g.*, a basic solution), acidic lysis solutions (*e.g.*, an acidic solution), EDTA, EGTA, surfactants, metal ions, cations, anions, chelators, and enzymes.

APPENDIX B

Marked-up Version of the Amended Claims Pursuant to 37 C.F.R. §1.121(c)(1)(ii)

1. A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer to a recipient mammal comprising contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, [and] determining binding of the set of binding agents to the Gram-negative bacterial antigen and the Gram-positive bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product, and identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria as useful for transfer to the recipient mammal.

7. A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in donor blood or blood product from a donor mammal for transfer to a recipient mammal comprising contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, [and] determining binding of the set of binding agents to the Gram-positive bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product, and identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria as useful for transfer to the recipient mammal.

blood

8. A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in donor blood or blood product from a donor mammal for

transfer to a recipient mammal comprising contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, [and] determining binding of the set of binding agents to the Gram-negative bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product, and identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacteria as useful for transfer to the recipient mammal.

14. A method for screening for the presence of a clinically relevant amount of bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, [and] determining binding of the set of binding agents to the Gram-negative bacterial antigen and the Gram-positive bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of bacteria in the donor tissue, and identifying the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of bacteria as useful for transfer to the recipient mammal.

17. A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, [and] determining binding of the set of binding agents to the Gram-positive bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor tissue and no binding indicates the absence of a clinically relevant

amount of Gram-positive bacteria in the donor tissue, and identifying the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria as useful for transfer to the recipient mammal.

18. A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, [and] determining binding of the set of binding agents to the Gram-negative bacterial antigen and the Gram-positive bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor tissue, and identifying the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacteria as useful for transfer to the recipient mammal.